

**CLAIMS**

What is claimed is:

1. A method of treating pain in a subject, the method comprising the steps of: implanting a controlled release drug delivery device in an implantation site in the body of the subject; and delivering systemically from said drug delivery device a formulation comprising fentanyl or a fentanyl congener in an amount effective to alleviate pain in the subject.
2. The method of claim 1; wherein the drug delivery device is implanted at a subcutaneous site.
3. The method of claim 1, wherein the formulation is delivered at a volume rate of from about 0.01  $\mu$ l/day to 2 ml/day
4. The method of claim 1, wherein the fentanyl or a fentanyl congener in the formulation is delivered at a rate of from about 0.01  $\mu$ g per hour to 200  $\mu$ g per hour.
5. The method of claim 1, wherein said delivering of the formulation is substantially continuous.
6. The method of claim 1, wherein the drug delivery device is coupled to a proximal end of a catheter for delivery of the formulation to a delivery site at a distance from the implantation site.
7. The method of claim 1, wherein the drug delivery device is a convective drug delivery device.

8. The method of claim 7, wherein the convective device is selected from the group consisting of an electromechanical pump, an electroosmotic pump, a hydrolytic system, a piezoelectric pump, an elastomeric system, a vapor pressure pump, an electrolytic pump and an osmotic bursting matrix.
9. The method of claim 7, wherein the convective device is an osmotic pump.
10. The method of claim 1, wherein the drug delivery device is a diffusion system.
11. The method of claim 1, wherein the drug delivery device is an erodible drug-comprising matrix.
12. The method of claim 1, wherein said delivering is for a period of from about 4 weeks to 12 months.
13. The method of claim 1, wherein the drug delivery device comprises an amount of fentanyl or fentanyl congener sufficient for alleviation of pain in the subject for a period of more than 3 days.
14. The method of claim 1, wherein the drug delivery device comprises an amount of fentanyl or fentanyl congener sufficient to provide for alleviation of pain in the subject for a period of more than 30 days.
15. The method of claim 1, wherein the drug delivery device comprises an amount of fentanyl or fentanyl congener sufficient to provide for alleviation of pain in the subject for a period of more than 100 days.

16. The method of claim 1, wherein the formulation comprises sufentanil.
17. The method of claim 16, wherein sufentanil is delivered at a rate of from about 0.01  $\mu\text{g}/\text{hr}$  to about 200  $\mu\text{g}/\text{hr}$ .
18. The method of claim 16, wherein the drug delivery device comprises an amount of sufentanil sufficient for alleviation of pain in the subject for a period of more than 2 days.
19. The method of claim 16, wherein the drug delivery device comprises an amount of sufentanil sufficient for alleviation of pain in the subject for a period of more than 20 days.
20. A method of treating pain in a subject suffering from pain, the method comprising: administering a formulation comprising fentanyl or a fentanyl congener to a subject, said administering being by systemic delivery at a volume rate of less than about 2 ml/day; wherein pain is alleviated in the subject.
21. The method of claim 20, wherein said administering is by implanting a drug delivery device at an implantation site in the subject.
22. The method of claim 20, wherein the implantation site is a subcutaneous site.
23. The method of claim 20, wherein the drug delivery device is a convective device.

24. The method of claim 23, wherein the convective device is selected from the group consisting of an electromechanical pump, an electroosmotic pump, a hydrolytic system, a piezoelectric pump, an elastomeric system, a vapor pressure pump, an electrolytic pump and an osmotic bursting matrix.
25. The method of claim 20, wherein the convective device is an osmotic pump.
26. The method of claim 20, wherein the drug delivery device is a diffusion system.
27. The method of claim 20, wherein the drug delivery device is an erodible drug-comprising matrix.
28. The method of claim 20, wherein systemic delivery is substantially continuous.
29. The method of claim 20, wherein the formulation is administered for a pre-selected administration period.
30. The method of claim 29, wherein the preselected administration period is from about 4 weeks to 12 months.
31. The method of claim 20, wherein the formulation comprises sufentanil.
32. The method of claim 31, wherein sufentanil is delivered at a rate of from about 0.01  $\mu$ g/hr to about 200  $\mu$ g/hr.
33. The method of claim 31, wherein the formulation is within a drug delivery device implanted in the subject.

34. The method of claim 33, wherein the drug delivery device comprises an amount of sufentanil sufficient for alleviation of pain in the subject for a period of more than 2 days.
35. The method of claim 33, wherein the drug delivery device comprises an amount of sufentanil sufficient for alleviation of pain in the subject for a period of more than 20 days.
36. The method of claim 20, wherein the drug delivery device is substantially completely implanted.
37. A device for the treatment of pain, comprising:  
an implantable controlled drug delivery device for implanting at an implantable site in a patient in need of pain treatment, the device comprising a formulation comprising fentanyl or a fentanyl congener;  
wherein the implantable device is suitable for delivery of fentanyl or fentanyl congener into the systemic circulation in an amount effective for treatment of pain in the subject.
38. The device of claim 37, wherein the device comprises an amount of formulation sufficient for delivery of an amount of fentanyl or fentanyl congener effective for treatment of pain in the subject for a period of at least about 3 days to about 10 days.
39. The device of claim 37, wherein the device comprises an amount of formulation sufficient for delivery of an amount of fentanyl or fentanyl congener effective for treatment of pain in the subject for a period of at least about 4 weeks.
40. The device of claim 37, wherein the device comprises an amount of formulation sufficient for delivery of an amount of fentanyl or fentanyl congener effective for treatment of

pain in the subject for a period of at least about 100 days.

41. The device of claim 37, wherein the device administers formulation at a rate of from about 0.01  $\mu\text{g}/\text{hour}$  to 200  $\mu\text{g}/\text{hr}$ .

42. The device of claim 37, wherein the formulation comprises sufentanil.

43. The device of claim 37, wherein the device is suitable for delivery of fentanyl or fentanyl congener at a rate of from about 0.01  $\mu\text{g}/\text{hr}$  to about 200  $\mu\text{g}/\text{hr}$ .

44. The device of claim 37, wherein the device is suitable for delivery of fentanyl or fentanyl congener at a volume rate of from about 0.01  $\mu\text{l}/\text{day}$  to 2  $\text{ml}/\text{day}$ .

45. The device of claim 37, wherein the drug delivery device comprises an amount of fentanyl or fentanyl congener sufficient for delivery for alleviation of pain in the subject for a period of more than 2 days.

46. The method of claim 37, wherein the drug delivery device comprises an amount of fentanyl or fentanyl congener sufficient for delivery for alleviation of pain in the subject for a period of more than 20 days.

47. The method of claim 37, wherein the drug delivery device comprises an amount of fentanyl or fentanyl congener sufficient for alleviation of pain in the subject for a period of more than 100 days.